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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
02/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/761,498	MICHON ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *101309*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-13,15,16,18-37 and 39-66* is/are pending in the application.

4a) Of the above claim(s) *10,29-36,41-58 and 62-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9,11-13,15,16,18-28,37,39,40,59-61 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *101309*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 10/13/09 in response to the non-final Office Action mailed 04/13/09.

Status of Claims

2) Claims 1, 4-7, 15, 37, 39 and 59 have been amended via the amendment filed 10/13/09.

Claims 1, 4-13, 15, 16, 18-37 and 39-66 are pending.

Claims 1, 4-9, 11-13, 15, 16, 18-28, 37, 39, 40, 59-61 and 66 are under examination.

Information Disclosure Statement

3) Acknowledgment is made of Applicants' information disclosure statement filed 10/13/09. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Prior Citation of Title 35 Sections

4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) to Specification

6) 37 CFR 1.75(d)(1) provides, in part, that 'the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'

Claims 1 and 16, as amended, include the limitation: 'non-naturally occurring protein'. The limitation lacks clear support or antecedent basis in the specification as filed.

Rejection(s) Withdrawn

7) The rejection of claim 1 made in paragraph 30(a) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

8) The rejection of claims 4-7, 15, 37 and 39 made in paragraph 30(b) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

9) The rejection of claim 16 made in paragraph 30(c) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

10) The rejection of claim 4 made in paragraph 30(e) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 39 made in paragraph 30(f) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claim 16 made in paragraph 30(g) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claim 59 made in paragraph 30(h) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

14) The rejection of claim 1 made in paragraph 30(d) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reasons set forth therein and herein below.

Applicants contend that they have amended the claim as suggested in the Office Action. However, only a part of suggested amendment has been made to the claim. The open claim

language 'comprising' permits the presence of any isolated polysaccharide or oligosaccharide that is acryloylated without N-de-acetylating and that is other than the earlier recited N-deacetylated and N-acryloylated polysaccharide or N-deacetylated and N-acryloylated oligosaccharide. Therefore, it is suggested again that Applicants replace the limitation 'the at least one N-acryloyl group of the polysaccharide or the oligosaccharide' in lines 11 and 12 of claim 1 with the limitation --the at least one N-acryloyl group of the N-deacetylated and N-acryloylated polysaccharide or the N-deacetylated and N-acryloylated oligosaccharide--.

15) The rejection of claim 37 made in paragraph 30(i) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reasons set forth therein and herein below.

Applicants contend that in light of the claim amendments, the rejection is moot. However, the claim as amended continues to include the indefinite and confusing limitation 'antibodies reactive against the bacteria …'. It is still unclear what precise functional property of the antibodies is encompassed in the limitation 'reactive against the bacteria'. See also the new rejection set forth below under 35 U.S.C. § 112, second paragraph.

16) The rejection of claims 4-9, 11-13, 15, 22-28, 37, 39, 40, 59, 61 and 66 made in paragraph 30(i) of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for the reason set forth therein.

Rejection(s) Maintained

17) The rejection of claims 1, 16 and the dependent claims 4-9, 11-13, 15, 18-28, 37, 39, 40, 59-61 and 66 made in paragraph 27 of the Office Action mailed 04/13/09 under 35 U.S.C. § 112, first paragraph, as containing new matter, is maintained for the reasons set forth therein and herein below.

Applicants contend that page 8, lines 27-29 of the specification state that after hydrolysis, the polysaccharide or oligosaccharide is N-acryloylated to the extent desired by using a variety of acryloylating agents, and provide the necessary support for the limitation 'at least one N-acryloyl group' of the polysaccharide or the oligosaccharide and for the replacement of 'at least one removed N-acetyl group with at least one N-acryloyl group'. Applicants opine that the phrase 'to the extent desired' indicates that at least one N-acryloyl group, but as many as the user

desires, may be added to the polysaccharide or oligosaccharide. Applicants state that further support for the recitation 'at least one acryloyl group' is provided by the specification at page 9, lines 30-32 that recites 'wherein the protein is linked to the polysaccharide or oligosaccharide through one or more sites on the polysaccharide or oligosaccharide'. Applicants opine that since linking would occur through the acryloyl group, this recitation is supported.

Applicants' arguments have been carefully considered, but are not persuasive. The phrase 'to the extent desired' is not equated with the meaning 'at least one' in the as-filed specification. Lines 30-32 of page 9 of the specification pertain to unmodified polysaccharide or oligosaccharide, and the one or more sites on the polysaccharide or oligosaccharide recited therein are not identified as one or more N-acryloyl groups. In fact, lines 3-5 of page 10 of the specification state that the points of attachment are between lysine or cysteine residues of the protein and the N-acryloyl "groups" of the polysaccharide or oligosaccharide, indicating support for the pleural N-acryloyl groups, but not for 'one … N-acryloyl group'. Note that the lower limit of the limitation 'at least one' is one. The claimed conjugate comprising the recited isolated polysaccharide or oligosaccharide having only one N-acryloyl group and being covalently attached to the protein as recited is required to be 'immunogenic' and elicit an immune response (includes cell mediated immune response) and immunoglobulins IgG, IgM and IgA specific to the polysaccharide or the oligosaccharide. The claimed 'vaccine' comprising such immunogenic conjugate is required to generate antibodies 'that are reactive against the bacteria … from which the polysaccharide or the oligosaccharide was isolated to confer immunity to said cell'. Note also that there is a difference between a vaccine and an immunogenic composition. A vaccine 'must be by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough'. *In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).* The instant specification fails to provide descriptive support for the claimed immunogenic conjugate, the pharmaceutical composition, or the vaccine product comprising the recited isolated polysaccharide or oligosaccharide having only one N-acryloyl group and being covalently attached to the protein as recited and a vaccine comprising the same. This is supported by Applicants' remark at the bottom of page 24 of their amendment/response filed 10/13/09 indicating that the efficient N-deacetylation for acceptable antigenicity is greater than 95%. The rejection stands.

18) The rejection of claims 25 and 40 made in paragraph 28 of the Office Action mailed 04/13/09 under 35 U.S.C § 112, first paragraph, as being non-enabled, is maintained for the reasons set forth therein and herein below.

On the bottom half of page 16 of their response filed 10/13/09, Applicants state that claims 25 and 40 'are newly cancelled in this response'. However, claims 25 and 40 have not been canceled and remain as pending claims under examination.

Applicants acknowledge that the use of combination vaccines involve optimizing of the claimed conjugates and the method of their administration. Applicants state that such optimization might include substitution of the carrier protein and are within the skill on the art coupled with the teachings provided by Applicants in the description of their invention. Applicants assert that the art clearly recognizes the advantages and in certain cases need to use multivalent vaccines and it would therefore be inappropriate to deny Applicants the right to claim their invention as broadly as it is likely to be applied. Applicants state that the use of combination vaccines has become a critical component of providing adequate vaccination protocols to very young children. Applicants cite the statement from Elliman D. *BMJ*, 326: 995-996, (2003) that 'using combination vaccines in the routine childhood programme in the United Kingdom amounts to giving 11 injections (24 in the United States), whereas if given separately, 27 (almost 70), would be needed'. Applicants acknowledge the recognition by Elliman that certain difficulties may arise developing combination conjugate vaccines, but cite Elliman's statement that some of these issues might not even be recognized except through good post marketing surveillance of the product. Applicants opine that for a vaccine to even get into a period of market surveillance would imply that during its development and initial marketing, those skilled in the art would have had at least a reasonable basis to believe the vaccine would be efficacious. Applicants cite a part of Guess H. *Epidemiological Reviews*, 21:89-95 (1999) and state that because vaccination is believed to be so critical, simultaneous administration of vaccines is recommended even without all of possible preapproval studies for all of the different possible combinations. Applicants submit that the strong endorsement to use simultaneous administration of vaccines supports Applicants' claims to multivalent vaccines. Applicants state that having provided those in the art with an efficient means of making conjugate vaccines, Applicants are entitled to claim the various ways in which their vaccines may be used.

Applicants' arguments have been carefully considered, but are not persuasive. '[T]o be enabling, the specification ….. must teach those skilled in the art how to make and use *the full scope of the claimed invention* without undue experimentation'. *Wright*, 999 F.2d at 1561 [Emphasis added], quoted in *Genetech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). Thus, 'there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed'. *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991), quoted in *Enzo Biochem, Inc. v. Calgene Inc.*, 188 F.3d 1362, 1372 (Fed. Cir. 1999). *Genentech Inc. v. Novo Nordisk* A/S (CAFC) 42 USPQ 2d 1001 clearly states: 'Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable'. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license".

As set forth previously, there is a lack of showing that a de-N-acetylated and a N-acryloylated *Streptococcus* Group B polysaccharide- or oligosaccharide-tetanus toxoid or diphtheria toxoid conjugate, a de-N-acetylated and a N-acryloylated *E. coli* K1 polysaccharide- or oligosaccharide-tetanus toxoid or diphtheria toxoid conjugate, and a meningococcus polysaccharide- or oligosaccharide-tetanus toxoid or diphtheria toxoid conjugate as claimed in the instant invention can be successfully combined with a second monovalent or multivalent protein component, such as, DTaP, or DTP, Td, DTap-Hib, DTaP-IPV-Hib, or combinations thereof, wherein the conjugate still remains optimally 'immunogenic' and produces antibodies reactive against *Streptococcus* Group B, *E. coli* K1, or meningococci to 'confer immunity to said cell'. Note that a vaccine 'must be by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough'. *In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).* In the instant case, there is no showing that the instantly claimed conjugate vaccine when combined with one or more of any of the recited second component or combinations thereof, would retain its immunogenic and protective functions as a vaccine or pharmaceutical composition and would effectively elicit optimal GBS-specific, *E. coli* K1-specific, or meningococcus-specific protective immune response, i.e., opsonophagocytic and/or bactericidal immune response. The Applicant-cited part of Guess H. 1999 is related to the simultaneous administration of art-known vaccines identified therein, but is not relevant to the

enablement of combining any new vaccine with the existing vaccines. As Guess H. 1999 teaches therein, the state of the art requires preapproval studies of 'new' vaccines to include data confirming safety and immunogenicity when the "new" vaccine is administered simultaneously with licensed vaccines. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). As set forth previously, this is important because the state of the art on combination vaccines at the time of the invention indicated the occurrence of potential interference by one or more added vaccine components. For instance, Barington *et al.* (*Infect. Immun.* 61: 432-438, 1993 – Applicants' IDS) taught that immunizations of conjugated polysaccharides and unconjugated (free) carrier protein (for example, TT in the instant case), lead to a non-epitope specific suppression of the antibody response not only to the carrier protein, but the polysaccharide as well. Corbel (*Biologicals* 22: 353-360, 1994 – Applicants' IDS) taught that the use of diphtheria and tetanus proteins as carriers for multiple polysaccharide conjugates may lead to epitope suppression of anti-polysaccharide responses (see abstract). Most importantly, the combining of DTaP and IPV or DTaP and IPV with a bacterial capsular polysaccharide-protein conjugate has been shown in the art to result in interference and a significant and pronounced reduction in immune response to IPV. For example, see page 1688 of Eskola *et al.* (*Lancet* 348: 1688-1692, 1996, of record), who concluded that '[t]he immunogenicity of all antigens must be tested before new combinations can be accepted for vaccination programmes …'. Eskola *et al.* used a conjugate produced by a method non-identical to Applicants' method and concluded that '[a]lthough all combinations proved safe, the poor immunogenicity of the Hib component when it was mixed with DTP-a in the two dose schedules studied here raises important questions about the immunonological mechanism of the interference seen and about its clinical relevance'. See first paragraph under 'Discussion'. Furthermore, Clemens *et al.* (*Ann. N Y Acad. Sci.* 754: 255-266, 1995) specifically taught the following: 'It follows that an enormous matrix of studies would be **required** to exhaustively exclude the possibility of interference when **a new vaccine** is considered for inclusion in simultaneous or combined immunization regimens in clinical practice.' See page

262 of Clemens *et al*. In the instant case, not one single combination composition or vaccine claimed in claims 25 and 40 is enabled. The rejection stands.

19) The rejection of claims 1, 4, 6-9, 11-13, 16, 18-21, 61 and 66 made in paragraph 32 of the Office Action mailed 04/13/09 under 35 U.S.C. § 102(b) as being anticipated by Pon RA (*The Study of Polysialic acid Conjugates*. Master's Thesis, University of Ottawa, pp. 1-251, UMI Dissertation Services, 1992 – Applicants' IDS) as evidenced by Kabat *et al*. (*J. Exp. Med.* 164: 642-654, 1986 – Applicants' IDS), is withdrawn in light of Applicants' amendment to the claims and/or the base claims.

20) The rejection of claims 1, 4, 6-9, 11-13, 22-24, 26-28, 37, 39, 61 and 66 made in paragraph 33 of the Office Action mailed 04/13/09 under 35 U.S.C. § 102(b) as being anticipated by Jennings *et al*. (WO 96/40239 - Applicants' IDS), is withdrawn in light of Applicants' amendment to the claims and/or the base claims.

21) The rejection of claims 59 and 60 made in paragraph 35 of the Office Action mailed 04/13/09 under 35 U.S.C. § 103(a) as being unpatentable over Pon RA (*The Study of Polysialic acid Conjugates*. Master's Thesis, University of Ottawa, pp. 1-251, UMI Dissertation Services, 1992 – Applicants' IDS) as applied to claim 1 or claim 16, is withdrawn in light of Applicants' amendment to the claims and/or the base claims.

Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

22) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

23) Claims 1, 16 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1 and 16, as amended, include the new limitation: 'non-naturally occurring protein'. Applicants point to lines 25-27 of page 9 of the specification for support, which are reproduced below:

> toxoid, synthetic protein containing lysine or cysteine residues, and the like. The carrier protein may be a native protein, a chemically modified protein, a detoxified protein or a recombinant protein. Conjugate molecules prepared according to this

However, this part of the as-filed specification does not provide descriptive support for the now recited generic broad limitation 'non-naturally occurring protein', which encompasses proteins other than those identified above. Therefore, the above-identified limitation in the claims is considered to be new matter. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

24) Claim 37 and the dependent claims 39 and 40 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 37, as amended, includes the new limitation: 'to confer immunity to said cell'. Applicants point to lines 1-6 and 14-17 of page 12 of the specification for support. However, these parts of the specification do not provide descriptive support for the vaccine composition as claimed which generates antibodies as recited 'to confer immunity to said cell'. Therefore, the above-identified limitation in the claim is considered to be new matter. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

25) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

26) Claims 1, 4-9, 11-13, 15, 16, 18-28, 37, 39, 40, 59-61 and 66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1 and 16, as amended, are vague, indefinite and confusing in the limitation: 'the polysaccharide or the oligosaccharide is isolated from bacteria .... wherein the polysaccharide or the oligosaccharide is .... synthetic', because it is unclear how a 'synthetic' polysaccharide or oligosaccharide can be 'isolated' from bacteria? Do the recited bacteria produce a 'synthetic' polysaccharide or oligosaccharide?

(b) Claim 37, as amended, is vague, indefinite and confusing in the limitation: 'confer immunity to said cell', because it is unclear how immunity can be conferred by the claimed vaccine 'to' said cancer cell as opposed to a subject or animal to whom the vaccine gets administered. Furthermore, are the vaccine-generated antibodies that are reactive against the elected bacteria species conferring immunity to 'said' cancer cell? Clarification is requested.

(c) Claim 39, as amended, is indefinite because it lacks proper antecedent basis in the limitation 'oligosaccharide is isolated'. For proper antecedence, it is suggested that Applicants replace the above-identified limitation with the limitation --the oligosaccharide is isolated--.

(d) Claims 1 and 16, as amended, are vague and indefinite in the limitation: 'non-naturally occurring protein' because it is unclear which proteins are encompassed within this limitation. Are non-isolated or non-purified native proteins, and fragments of naturally occurring proteins encompassed within the scope of this limitation? Does isolated tetanus toxin or naturally toxoided non-cellular tetanus toxin qualify as a 'non-naturally occurring protein'?

(e) Claims 4-9, 11-13, 15, 18-28, 37, 39, 40, 59-61 and 66, which depend directly or indirectly from claim 1 or claim 16, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Claim Objection(s)

27) Claim 61 is inconsistent with claims 4 and 5 in the non-italicized limitation 'Streptococcus'. To be consistent with the practice in the art, it is suggested that Applicants italicize the name of bacteria recited in line 4 of the claim.

Remarks

28) Claims 1, 4-9, 11-13, 15, 18-28, 37, 39, 40, 59-61 and 66 stand rejected.

29) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

30) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

31) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

32) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

February, 2010